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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,135	12/12/2003	John Winterbottom	2004367-0031	1936
24280	7590	06/26/2006	EXAMINER	
CHOATE, HALL & STEWART LLP			DAVIS, RUTH A	
TWO INTERNATIONAL PLACE			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	
			1651	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/735,135	Applicant(s) WINTERBOTTOM ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-121 is/are pending in the application.
- 4a) Of the above claim(s) 39-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/04/8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1 - 38 in the reply filed on May 18, 2006 is acknowledged.

Claims 39 – 121 are withdrawn from consideration; claims 1 – 38 have been examined on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a composite implant, however are rendered vague and indefinite for reciting “is adapted” because the phrase implies that steps are taken to alter, or make, the implant in a particular way. Since the claims do not recite how the composite is “adapted”, it is unclear if the claims are missing a critical feature of the invention.

Claim 1 and its dependents are confusing for reciting “predetermined conditions” because these conditions have not been adequately defined by the specification.

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Claims 11 and 12 are indefinite for reciting “is set” and “becoming set” because it is unclear what these phrases intend to convey as it pertains to the implant. Specifically, it is unclear if applicant means the implant is no longer formable, or if the implant is set, or ready, for implantation.

Claims 13, 14 and 22 are confusing because it is unclear if the claims contain a Markush group, as the proper language is not recited. Moreover, it is unclear what the composite further comprises.

Claim 16 is rendered vague and indefinite for reciting “is adapted” because the phrase implies that steps are taken to alter, or make, the implant in a particular way. Since the claims do not recite how the composite is “adapted”, it is unclear if the claims are missing a critical feature of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 – 38 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by

Boyce et al. (US 2002/0035401 A1).

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Applicant claims a composite osteoimplant comprising a polymer and bone-derived particles, wherein the composite is formable during or immediately before implantation. The composite is formable at room temp; and is not formable at 37C but is formable when heated to greater than 40, 45, 50, 55, 60, 70, 80 or 90C. The composite is set by increasing crosslinking density of the polymer; and further comprises a monomer, wherein the composite is set when the monomer is covalently bonded to the polymer. The composite further comprises at least one of bone marrow, biomolecules, small molecule, bioactive agent, calcium phosphate, calcium carbonate, cells; one of nucleic acid vector, mesenchymal stem cells, osteoblasts, osteoclasts, fibroblasts; the nucleic acid vector increase cell production of BMP. The osteoimplant is constructed to be irrigated after implantation without changing shape; the bone derived particle is selected from nondemineralized bone particles, partially demineralized bone particles, superficially demineralized bone particles, demineralized bone particles or mixtures; the bone derived particles are obtained from cortical bone, cancellous bone, corticocancellous bone, or mixtures thereof; or the bone derived particles are from autologous bone, allogenic bone, xenogenic bone, transgenic bone or mixtures thereof. The osteoimplant has 10 – 99% bone derived particles, or 25 – 50%; a surface of the bone derived particles is modified with a biomolecules, small molecule, bioactive agents, non-biologically active material or any combination; that is linked by a coupling agent. The bone derived particles are covalently linked to one another; the collagen fibers at the surface of the bone derived particles are exposed wherein the collagen are partially or fully separate from one another; and the exposed fibers are derivatized with a biomolecule, small molecule, bioactive agent, non-biologically active material or any combination. The polymer is biodegradable, non-biodegradable, copolymers thereof, or

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any combination thereof, is selected from a disclosed group. The bone derived particle and polymer are linked with a coupling agent; the implant has a particular shape from a disclosed group; comprises a plurality of joined pieces joined with adhesive, mechanical fastener, ultrasonic bonding; the composite is formed in a mold; the distribution of the bone derived particles are not uniform; a portion of the bone derived particles are elongate and are arranged isotropically or anisotropically and has different alignment between portions of the composite.

Boyce teaches a composite osteoimplant comprising bone derived particles (abstract) and polymers (p.5), wherein the composite is formable during or just prior to implantation (abstract, 0014). The composite comprises monomers such as glycerol (0080), calcium phosphate (0063), biomolecules, small molecules, bioactive agents, cells, mesenchymal stem cells, bone marrow, nucleic acid vectors, BMPs, and bone promoters (0068-0072). The composite is adapted to be irrigated and not change shape (0034-0038). The bone derived particles may be non-demineralized, demineralized, partially demineralized (0060,0063); are obtained from cortical bone, cancellous bone, corticocancellous bone, autologous, allogenic, xenogenic or transgenic origin (0059); and is about 5 – 100%, 20 – 99%, or 40 – 85% of the composite (0050). The bone derived particles may further have biomolecules linked to the surface with coupling agents such as adhesives (0068-0072,0087) and the composite further comprises collagen fibers (0064). The polymers are selected from the disclosed group (p.5); the shape of the implant is selected from the disclosed group (p.8); and the implant has several pieces joined together via the claimed methods (0087). Finally the bone derived particles may be elongate (0025) and can be arranged into any pattern (0016-0020, 0043.)

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Although the reference does not teach the composite is formable at the claimed temperatures, becomes set when adding particular components, or increases BMP production, the composites are the same. Thus, the composite of the prior art must intrinsically exhibit the properties claimed by applicant. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 – 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34 - 83 of copending Application No. 10/681,651. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain specific coupling agents, and overlapping amounts of ingredients that would have been obvious to optimize by a person of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1 – 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51 - 116 of copending Application No. 10/639,912. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain specific coupling agents, and overlapping amounts of ingredients that would have been obvious to optimize by a person of ordinary skill in the art..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 22, 2006
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A handwritten signature in black ink, appearing to read 'Ruth A. Davis', with a stylized, cursive script.

RUTH A. DAVIS
PATENT EXAMINER